

REMARKS

Claims 1-4, 6-9, 11-15, and 22 are pending in the instant application. Claims 1, 6, and 11-15 have been amended. Claims 17-21 have been cancelled. Support for the amendments comes from original claims 1-21, and in paragraphs [0012], [0013], [0014], and [0067].

The following issues are outstanding in the instant application:

- Claims 1-4, 8-9, 12-15, and 17-22 have been rejected under 35 U.S.C. § 112, paragraph 1, as allegedly not being supported by the specification.
- Claims 1-4, 6-9, 11-15, and 17-22 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 4,851,221 (Pak *et al.*)

I. 35 U.S.C. § 112 issues

Claims 1-4, 8-9, 12-15, and 17-22 have been rejected under 35 U.S.C. § 112, paragraph 1, as allegedly not being supported by the specification. Applicant respectfully traverses.

Applicant has amended claims 1, 6, and 11-15 without prejudice or acquiescence in order to advance the prosecution of the instant application. Applicant notes that support for the amendments may be found in original claims 1-21, and in paragraphs [0012], [0013], [0014], and [0067].

Applicant asserts that while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981). The Examiner's remark regarding alleged toxicity of claimed ranges is not pertinent to issues related to the patentability of the claimed invention.

Applicant respectfully requests withdrawal of the 35 U.S.C. § 112, paragraph 1 rejection of claims 1-4, 8-9, 12-15, and 17-22, as it is moot in light of the amendments and remarks herein.

I. 35 U.S.C. § 102 issues

The Examiner has rejected claims 1-4, 6-9, 11-15, and 17-22 under 35 U.S.C. § 102(b) as allegedly anticipated by Pak *et al.* Applicant respectfully traverses.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Examiner cites Pak *et al.*, which teaches use of calcium for treating osteoporosis, hypertension, bone loss, hypoparathyroidism, and hyperphosphatemia. Pak *et al.* does not teach the step of measuring the high-density lipoprotein level in said woman, or the step of measuring the ratio of high-density lipoprotein to low-density lipoprotein in said woman. As Pak *et al.* does not teach all the limitations of the claimed invention, there is no anticipation, and Applicant requests withdrawal of the rejection under 35 U.S.C. § 102(b).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02194US0 from which the undersigned is authorized to draw.

Dated: July 14, 2004

Respectfully submitted,

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